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8 November 2002

Mr. Mark Ransick
Staff Test Engineer – Materials
Research & Development
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242-2839

Subject: Microscopical Examination of Reprocessed Surgical Instruments
Re: McCrone Associates Project MA38631

Dear Mr. Ransick:

We have completed our analysis of the above referenced samples. This analysis was performed under the authorization of your purchase order # 561383894-01. The following report summarizes our methodology and the results of our analysis.

Samples

A total of 34 instruments were received by McCrone Associates over a three month period starting 8 May 2002 and ending 7 July 2002. The instruments received are identified in Table I. These instruments were designed for one-time use, but have been cleaned and packaged for reuse. You asked us to examine these instruments for any signs of use and to identify the compositions of any residues.

On 8 May 2002, I met with you at our facility, and you brought several brand new instruments in their manufacturers' original packaging and 25 reprocessed instruments. We examined the never-used instruments and you familiarized me with the use of each instrument. You pointed out locations on each instrument, which may be prone to collecting residues, where special care should be taken during our examination. We also grouped the reprocessed instruments into general categories in order to facilitate a more organized approach to the analysis of the instruments.

Analysis

As a guide for analysis, we received several protocols describing the criteria each instrument type should meet in order to pass the requirements as a clean instrument. The four protocols which were used are as follows:

Appendix A: Test Specification for Laparosonic Shears
Appendix D: Test Specification for Ligaclip Endoscopic Rotating Multiple Clip Appliers
Appendix E: Test Specification for Endoscopic Staplers, 35-45 mm
Appendix F: General Test Specification

Before the packaging of any of instrument was opened, images were taken with a digital camera to document the condition of the instruments (as received), the type of packaging and the information provided on the labeling. Original packaging from many of the instruments consisted of a rigid plastic tray; however, packaging of the reprocessed instruments is a plastic bag reinforced with a cardboard support. Since the instruments were repackaged in non-rigid containers, rubber caps were placed on the sharp tips of the instruments. Some of these protective caps from the tips of the instruments were dislodged, marring the packaging. In some cases, the dislodging of the protective caps possibly caused fine pin pricks in the packaging. To document this damage to the packaging, close-up images were also taken and are saved on a CD-ROM which is included with this report.

Photocopies of the test protocols were made and used as a worksheet when examination of the instruments was performed. A copy of each filled-in worksheet is provided in the Appendix to this report. Once the packaging was opened, the instruments were examined using a stereomicroscope. Any suspected residues were isolated for analysis using a sharpened tungsten needle. Residues suspected to be blood were placed on a moistened Hemastix® test trip. The Hemastix test strip is a presumptive color test, which is very sensitive and used for the testing of blood in urine. When necessary, the isolated residue was also prepared for analysis by infrared microspectroscopy (FTIR) and/or elemental analysis by energy dispersive x-ray spectroscopy (EDS) on the scanning electron microscope. The stereomicroscope was also equipped with a digital camera and, in some cases, images were taken to document the residue observed on the instrument. The images taken through the stereomicroscope are formatted in a PowerPoint presentation provided on a CD-Rom and hard copies of these low magnification photomicrographs are provided in Figures 1 through 43. A summary of particles and residues isolated from each instrument for analysis is provided in Table II. All of the infrared spectra and EDS spectra of the analyzed residues are provided in Figures 44 through 71.

Many of the instruments have a plastic sheath covering the shaft mechanism. In order to observe if any residues have migrated under the sheath, the sheath was cut with a razor blade approximately 2 to 3 inches and pulled back to observe the surface of the shaft. Some of the instruments were observed to have reddish/brown particulate, which was often identified as iron oxide. Images were taken showing examples of corrosion observed on many of the instruments.

You requested we take careful observation of the two stapler devices (R0076 and R0079) received on 14 June 2002 which had no staple cartridges. In particular, you were interested in evidence of material being lodged in the pockets of the anvil. Careful observation was made and no evidence of material was observed.

Instrument R0079 was seen to have the most obvious contamination. The handle of this instrument was seen coated with a red residue. When a portion of the residue was isolated and analyzed by energy dispersive x-ray spectrometry, it was identified as iron oxide. After the initial examination, the handle of the instrument was broken open and revealed the source of the iron oxide to originate from the spring and metal trigger mechanism. Samples were taken of the corroded mechanism for analysis by energy dispersive x-ray spectroscopy, showing the material to be mainly iron oxide with traces of silicon, sulfur and manganese. Images of the rusted spring mechanism are provided in Figures 27 through 29.

A preliminary report was faxed to you on 10 September 2002, and you discovered an error in the report in the analysis of instruments R0058 and R0076. The protocol from Appendix E was used in their examination instead of the one in Appendix B. The protocols are similar; however, there are some differences in the section outlining the evaluation of the performance of the instrument. The observations made for these two instruments using Appendix E were compared with the protocol in Appendix B and both instruments passed the requirements in sections B.1 and B.3. However, observations for the instructions outlined in B2.1 through B2.6 could not be made since the instruments were already fired.

Thank you for consulting McCrone Associates. If you have any questions concerning this report, please do not hesitate to call.

Sincerely,

Mark A. Bukantis

Mark A. Bukantis
Research Microscopist

MAB:jc
Enclosures
Ref: MA38631; P.O. 561383894-01

TABLE I

List of Reprocessed Instruments Received for Analysis (MA38631)

Trocar Part Number	Product Code	Product Description	Reprocessor	Date Received
R0050	511SD	Endopath Trocar, Dilating Tip with Stability Sleeve, 11 mm	Alliance Med.	8 May 2002
R0051	511SD	Endopath Trocar, Dilating Tip with Stability Sleeve, 11 mm	Alliance Med.	8 May 2002
R0052	5DCS	Endopath Scissors, Curved, with Unipolar Electrocautery, 5 mm	Alliance Med.	8 May 2002
R0053	5DCS	Endopath Scissors, Curved, with Unipolar Electrocautery, 5 mm	Alliance Med.	8 May 2002
R0054	5DCS	Endopath Scissors, Curved, with Unipolar Electrocautery, 5 mm	Alliance Med.	8 May 2002
R0055	5BB	Endopath Endoscopic Babcock, 5 mm	Alliance Med.	8 May 2002
R0056	5DCS	Endopath Scissors, Curved, with Unipolar Electrocautery, 5 mm	Alliance Med.	8 May 2002
R0057	ER320	Ligaclip Med/Lg ERCA	Vanguard	8 May 2002
R0058	TL90	Proximate Linear Stapler 90, Heavy Wire	Vanguard	8 May 2002
R0059	512SD	Endopath Trocar, Dilating Tip with Stability Sleeve, 12 mm	Vanguard	8 May 2002
R0060	512SD	Endopath Trocar, Dilating Tip with Stability Sleeve, 12 mm	Vanguard	8 May 2002
R0061	35 NLT	5 mm Trocar, Bladeless with Stability Sleeve	Alliance Med.	8 May 2002
R0062	5DCS	Endopath Scissors, Curved, with Unipolar Electrocautery, 5 mm	Alliance Med.	8 May 2002
R0063	5DSG	Endopath Grasper, 5 mm	Alliance Med.	8 May 2002
R0064	5DSG	Endopath Grasper, 5 mm	Alliance Med.	8 May 2002
R0065	5DCS	Endopath Scissors, Curved, with Unipolar Electrocautery, 5 mm	Vanguard	8 May 2002
R0066	5DCS	Endopath Scissors, Curved, with Unipolar Electrocautery, 5 mm	Vanguard	8 May 2002
R0067	DSG23	5 mm Grasper for unipolar cautery	Alliance Med.	8 May 2002
R0068	ER320	Ligaclip Multiple Clip Applier	Alliance Med.	8 May 2002
R0069	LCSC5	Harm. Scalpel, Laproscopic Curved Shears	Alliance Med.	8 May 2002
R0070	5DCD	5 mm curved dissector, cautery	Alliance Med.	8 May 2002
R0071	5DCS	Endopath Scissors, Curved, with Unipolar Electrocautery, 5 mm	Alliance Med.	8 May 2002
R0072	EZ45	Stapler	Vanguard	8 May 2002
R0073	ECS29	ILS Endoscopic Circular Stapler	Medical Device Services, Inc.	8 May 2002
R0074	5DSG	Endopath Grasper, 5 mm	Medical Device Services, Inc.	8 May 2002
R0075	MCM20	Stapler Multiclip Appl 2Clip Appliers Ligaclip Med/Long	SteriMed, Inc.	14 June 2002
R0076	TLH90	Stapler Proximate Linear Reloadable Heavy Wire, 90 mm (no cartridge in instrument)	SteriMed, Inc.	14 June 2002
R0077	AL326	Stapler Multiclip Applier Ligaclip Allport	SteriMed, Inc.	14 June 2002
R0078	5DSG	Endopath Grasper, 5 mm	SteriMed, Inc.	14 June 2002

TABLE I - continued

List of Reprocessed Instruments Received for Analysis (MA38631)

Trk #	Product Code	Product Description	Reprocessor	Date Received
R0079	ATW45	Reload Vascular/Thin WH (no cartridge in instrument)	SteriMed, Inc.	14 June 2002
R0080	5DCS	Endopath Scissors, Curved, with Unipolar Electrocautery, 5 mm	SteriMed, Inc.	14 June 2002
R0081	TLC55	Linear Cutter, 55 mm	SteriMed, Inc.	7 July 2002
R0082	5DCS	Endopath Scissors, Curved, with Unipolar Electrocautery, 5 mm	Alliance Med.	7 July 2002
R0083	5DCS	Endopath Scissors, Curved, with Unipolar Electrocautery, 5 mm	Alliance Med.	7 July 2002

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TABLE II

Summary of Analysis of Reprocessed Instruments (MA33831)

Trk #	Product Code	Protocol	Material Observed	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
R0050	511SD	Appendix F	None						No
R0051	511SD	Appendix F	None						No
R0052	5DCS	Appendix A	Slight brown discoloration under plastic sheath		Figures 1, 2				No
R0053	5DCS	Appendix A	Large flake (~1 mm) pressed flat with fibers on plastic sheath	Acrylic resin	Figures 3, 4	Figure 44			No
R0054	5DCS	Appendix A	Amorphous flake removed from the blade	Cellulose	Figures 5, 6	Figure 45			No
R0055	5BB	Appendix A	None						No
R0056	5DCS	Appendix A	Amorphous flake from blade	Cellulose		Figure 46		Protective cap off blade; plastic packaging bag was pierced by blade	No
			Red fiber	Red cotton fiber	Figure 7	Figure 47			
R0057	ER320	Appendix D	None					Cardboard insert in bag; plastic cap was off tip of instrument; bag was intact Contained 20 clips	No
R0058	TL90	Appendix E	None					Doubled bagged with cardboard insert	No
R0059	512SD	Appendix F	None						No
R0060	512SD	Appendix F	None						No
R0061	35NLT	Appendix F	Tan/brown residue	Mixture of protein and unknown ester	Figures 8-11	Figure 48		Tested (-) for blood	No
R0062	5DCS	Appendix A	Dark material between blades	Similar to an alkyd enamel	Figures 12, 13	Figure 49			No
R0063	5DSG	Appendix A	None						No
R0064	5DSG	Appendix A	Red/brown flake on sheath (near center)	Cellulose		Figure 50			No
R0065	5DCS	Appendix A	None					Blade had areas of heavy lubricant	No
R0066	5DCS	Appendix A	Dark soft material on edge of blade	Poly(styrene: acrylate ester)		Figure 51			No

TABLE II - continued

Summary of Analysis of Reprocessed Instruments (MA38631)

Trk #	Product Code	Protocol	Material Observed	Identification of Isolated Material	Images	Infrared Spectra	EDS Spectra	Comments	Tissue or Body Fluids Detected
R0067	DSG23 ✓	Appendix A	None						No
R0068	ER320 ✓	Appendix D	None					✓ Protective cap off instrument tip; bag intact Contained 20 clips	No
R0069	LCSC5 ✓	Appendix A	Red/brown residue on Teflon pad	✓ Teflon with red/brown particles	Figure 14	Figure 52		✓ Protective cap off instrument tip; bag intact Teflon pad was attached	No
R0070	5DCD ✓	Appendix A	Colorless residue on jaws of instrument	✓ Cellulose	Figure 15	Figure 53			No
R0071	5DCS ✓	Appendix A	Dark material under plastic sheath	✓ Protein	Figure 16				No
R0072	EZ 45 Stapler	Appendix E							No
R0073	ECS29 Circular Stapler ✓	Appendix E	None						No
R0074	5DSG ✓ Endopath grasper	Appendix A	✓ Tan residue with metallic flakes on jaws of instrument	IR indicates inorganic, possibly iron oxide	Figures 17, 18	Figure 54			No
			✓ Colorless residue	Protein		Figure 55			No
			✓ Tan residue	Unidentified ester		Figure 56			No
R0075	MCM20 ✓	Appendix D	None					✓ 13 clips	No
R0076	TLM90 ✓	Appendix E	None					✓ Handle found in closed position; no cartridge	No
R0077	AL326 ✓	Appendix D	None					21 clips	No
R0078	5DSG ✓	Appendix A	✓ Tan material surrounding nick in sheath	Protein (possibly skin flake)	Figures 19, 20	Figure 57		No blood	No
			✓ Colorless beads on tip of instrument		Figures 21, 22				No
			✓ (Tan) material on metal under sheath	Mixture of protein and an unknown	Figure 23	Figure 58		No blood	No

TABLE II - continued

Summary of Analysis of Reprocessed Instruments (MA38631)

Trk #	Product Code	Protocol	Material Observed	Identification of Isolated Material	Images	Infrared Spectra	EDS Spectra	Comments	Tissue or Body Fluids Detected
R0079	ATW45	Appendix E	Rust colored material on locking button	Acrylic resin iron oxide	Figure 24	Figure 59	Figure 62	The acrylic resin is probably the plastic from the handle	No
			Rust colored material surrounding button	Iron oxide corrosion	Figure 25	Figure 60	Figure 63		No
			Orange stain on staple anvil	(+) Hemastix® test; residue is a mixture of Teflon and a hydrocarbon	Figure 26	Figure 61		Sometimes metal oxides may cause false positive results with the Hemastix test strip	Possibly blood
R0080	5DCS	Appendix A	None					Nicks and scratches in the sheath; no tissue observed	No
R0081	TLC55	Appendix E	Orange/red material on several metal surfaces	Mixture of iron oxide, Teflon, and a hydrocarbon	Figures 32, 33, 34 Figures 35, 36, 37	Figure 68 Figure 69	Figures 64, 65 Figures 66, 67	Instrument appears to have been fired; the trigger handle was depressed; no cartridge in the instrument	No
R0082	5DCS	Appendix A	Dark red residue under sheath covering shaft (~½ inch from the mechanism)	Iron oxide		Figure 70	Figure 71	No cover on instrument tip; scratches in bag Very low levels of chlorine detected	No
R0083	5DCS	Appendix A	None					Protective cap off instrument tip; bag intact	No